

Image  
1653

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April 15<sup>th</sup> 2004

Dr. David Lukton  
Commissioner of Patents  
USPTO  
Patent Applications  
Washington DC 20231  
Tel: 703-308-3213.

Ref: 09/725,030

Dear Dr. David Lukton:

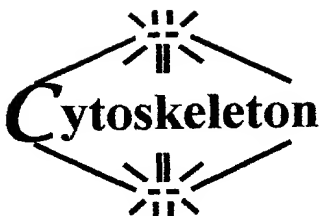
We did not receive a response to the additional information that we sent on 1.1.2004, a copy of which is attached. Please respond asap, thank you.

Yours sincerely,

Ashley Davis



*Filed 1-5-04  
703 872 9306*



*5 pages*

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January 1st 2004

Dr. David Lukton  
Commissioner of Patents  
USPTO  
Patent Applications  
Washington DC 20231  
Tel: 703-308-3213.

Ref: 09/725,030

Dear Dr. David Lukton:

With respect to our previous commincations about the applicability of claiming a compound and a mechanism, I wanted to bring your attention to the attached US patent # 6660767. In the inventors' claims it clearly states that "stabilizing microtubules" is the mechanism to be claimed. Likewise we are claiming that "S-phase arrest" is the mechanism. In addition the inventors clearly claim a compound "coumarin" in addition to this mechanism. Likewise we are claiming a compound "iodine acetamido benzoyl ethyl acetate". In addition the inventors claim "in combination with [eight other] compounds" (claim13) which they have clearly not tested, but your advice was to remove the unknown "other disease targets" from our claims list as unproven? Finally the aforementioned patent was applied for in 2-1-2001 and approved in 12-9-2003 which is two years and ten months. Currently our application has been pending for three years and three months.

We are looking for parity between our application and other approved patents we hope this extra information will assist this process.

Yours sincerely,

Ashley Davis,

Cytoskeleton Inc.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First named inventor: Ashley Davis

Application no.: 09/725,030 Amendments #5

Filed: 11/29/00

Examiner: Lukton, D

Title: Anti-S-phase tubulin ligands

Art Group: 1653

ADDITIONAL INFORMATION

Mailed to: Box Amendment, Commissioner for Patents, Mail Stop AF, Arlington VA 22202.

January 1<sup>st</sup> 2004

Dr. David Lukton  
Commissioner of Patents  
USPTO  
Patent Applications  
Washington DC 20231  
Tel: 703-308-3213.

Ref: 09/725,030

Dear Dr. David Lukton:

In response to the Office communication dated 6-20-2003 and our reply on 8-20-2003 with respect we submit the additional information.

With respect to our previous communications about the applicability of claiming a compound and a mechanism, I wanted to bring your attention to the attached US patent # 6660767. In the inventors' claims it clearly states that "stabilizing microtubules" is the mechanism to be claimed. Likewise we are claiming that "S-phase arrest" is the mechanism. In addition the inventors clearly claim a compound "coumarin" in addition to this mechanism. Likewise we are claiming a compound "iodine acetamido benzoyl ethyl acetate". In addition the inventors claim "in combination with [eight other] compounds" (claim13) which they have clearly not tested, but your advice was to remove the unknown "other disease targets" from our claims list as unproven, doesn't this constitute an idea? Finally the aforementioned patent was applied for in 2-1-2001 and approved in 12-9-2003 which is two years and ten months. Currently our application has been pending for three years and three months.

We are looking for parity between our application and other approved patents we hope this extra information will assist this process.

Ashley Davis, V-P, Cytoskeleton Inc.

## Abstract.

*Primary Examiner:* Reamer; James H.

*Attorney, Agent or Firm:* Jacobson Holman PLLC, Sundby; Suzannah K.

### ***Government Interests***

## STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

This invention was made with Government support under Grant No. R/MP-81, awarded by the National Oceanic & Atmospheric Administration (NOAA) California Sea Grant. The Government has certain rights in this invention.

### ***Parent Case Text***

## CROSS REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional Patent Application No. 60/283,366 filed Apr. 13, 2001, and U.S. Provisional Patent Application No. 60/265,576 filed Feb. 2, 2001, both of which name Robert S. Jacobs, Leslie Wilson, and Hamta Madari as co-inventors and are herein incorporated by reference.

### ***Claims***

We claim:

1. A method of stabilizing microtubules in a subject comprising administering at least one coumarin compound or a derivative thereof to the subject.
2. The method of claim 1, wherein the subject is a cell or organism.
3. The method of claim 2, wherein the organism is a mammal.
4. The method of claim 3, wherein the mammal is human.
5. The method of claim 1, wherein the coumarin compound is coumarin, dicoumarol, 7-hydroxycoumarin (umbelliferone), 6,7-dihydroxycoumarin (esculetin), 3,6,7 trihydroxy coumarin, warfarin, or warfarin sodium.
6. A method of modulating microtubules in a subject comprising administering at least one coumarin compound or a derivative thereof to the subject.
7. The method of claim 6, wherein the subject is a cell or organism.
8. The method of claim 7, wherein the organism is a mammal.

<http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&p=1&u=/netahtml/...> 1/5/2004

9. The method of claim 8, wherein the mammal is human.
10. The method of claim 9, wherein the coumarin compound is coumarin, dicoumarol, 7-hydroxycoumarin (umbelliferone), 6,7-dihydroxycoumarin (esculetin), 3,6,7 trihydroxy coumarin, warfarin, or warfarin sodium.
11. The method of claim 1, wherein the coumarin compound is administered in the form of a pharmaceutical composition which further comprises a pharmaceutically acceptable salt or prodrug thereof, at least one supplementary compound, and a pharmaceutically acceptable excipient.
12. The method of claim 11, wherein the supplementary compound is an antineoplastic agent, an antiproliferative agent, an anti-inflammatory agent, or an anti-fungal agent.
13. The method of claim 11, wherein the supplementary compound is taxol, estramustine, taxotere, vinblastine, vincristine, discodermolide, griseofulvin, or amphotericin B.
14. The method of claim 1, wherein stabilizing the microtubules in the subject treats, prevents, or inhibits a disease or disorder associated with microtubule formation or microtubule function in the subject.
15. The method of claim 14, wherein the disease or disorder is a hyperproliferative or cystic disease.
16. The method of claim 14, wherein the disease or disorder is cancer, Alzheimer's disease, atherosclerosis, restenosis, or gout.
17. The method of claim 1, wherein stabilizing the microtubules modulates the cell cycle of a cell in the subject.
18. The method of claim 1, wherein stabilizing the microtubules treats, prevents, or inhibits cancer in the subject.
19. The method of claim 18, wherein the coumarin compound is not coumarin, 7-hydroxycoumarin, warfarin, or warfarin sodium.
20. The method of claim 1, wherein stabilizing microtubules treats, prevents, or inhibits a disease or disorder associated with microtubule formation or microtubule function in the subject and the coumarin compound has a basic structural formula ##STR7##  
for a backbone structure, wherein the benzene ring, the pyrone, or both may further comprise at least one substituent.
21. The method of claim 1, further comprising administering an antineoplastic agent, an antiproliferative agent, an anti-inflammatory agent, or an anti-fungal agent.
22. The method of claim 1, further comprising administering a supplementary compound.
23. The method of claim 22, wherein the supplementary compound is a taxol, estramustine, taxotere, vinblastine, discodermolide, griseofulvin, or amphotericin B.